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No. 06-179

IN THE
Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

SUPPLEMENTAL BRIEF FOR PETITIONERS

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Petitioners Charles and Donna Riegel file this supplemental brief in response to the amicus curiae brief of the United States on May 23, 2007.

In 1997, the government told the Court that the question whether section 360k(a) of the Medical Device Amendments ("MDA") expressly preempts state-law claims seeking damages for injuries caused by medical devices "involves an issue of substantial importance that has divided the lower courts" and that "[t]he current division among the lower courts on that issue would normally provide a strong justification" for the Court's review. Br. for the U.S. as Amicus Curiae in *Smith Indus. Med. Sys. v. Kernats*, No. 96-1405, at 9, 18 (Dec. 2007) ("U.S. Br. in *Kernats*"). Today, indisputably, the division among the lower courts remains. Indeed, the two principal cases on the no-preemption side of the conflict post-date the filing of the Solicitor General's brief in *Kernats*. *See Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999); *Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999). What has changed since 1997 is the government's view on the merits of the question presented. The government's inconsistency on this question of statutory meaning only underscores the need for this Court to resolve the question presented.

1. The government agrees that the lower courts are divided over the answer to the question presented. Like petitioner Medtronic, the government (at 18) asks the Court not to bother with the conflict because there are more courts on one side of it than on the other. If this circumstance warranted denial of petitions for certiorari, then this Court would never have granted the petitions in *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-68 (2000); *Medtronic v. Lohr*, 518 U.S. 470 (1996), or *Cipollone v. Liggett Group*, 505 U.S. 504 (1992)—all of which resolved lopsided splits concerning express preemption of tort

claims by rejecting the holdings of a majority of the lower courts.

Also like Medtronic, the government (at 19) asks the Court to overlook the undisputed conflict because it might simply go away. As discussed in Petitioners' Reply (at 1-2), this speculation is unfounded. Nonetheless, referring to *Goodlin* and *Weiland*, the government (at 20) repeats Medtronic's suggestion that the Eleventh Circuit and the Illinois Supreme Court are likely to overrule their own holdings that section 360k(a) does not expressly preempt damages claims involving premarket approval ("PMA") devices merely because they are in the minority. Yet those courts have long been in the minority; and, after more than eight years, neither has intimated that it is dissatisfied with its minority view.[1]

The government (at 18-19 n.5) also tries to distinguish the cases holding that state-law damages claims are not sufficiently specific to prompt preemption under section 360k(a), but neither of its distinctions survives scrutiny. First, the government points out, as did Medtronic, that some of those cases did not involve PMA devices. To begin with, some of those cases *did* involve PMA devices. *See, e.g., Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997), *review denied*, 961 P.2d 217 (Or. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386 (Wash. Ct. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998). In any event, the government's

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[1] In this regard, the government fails to acknowledge the federal district court and state appellate court decisions that, like the Eleventh Circuit and the Illinois Supreme Court, have held that PMA is not a preemptive requirement under section 360k(a). *See* Pet. 15-16 (citing cases).

distinction is irrelevant because consideration of the state-law side of the preemption analysis does not turn on the type of device at issue, but rather on the fact that the state-law "requirements" at issue are too general to give rise to preemption under *Lohr*. *See* 518 U.S. at 500. These decisions squarely conflict with the decisions of courts that have held that section 360k(a) does preempt state laws of general applicability. *See* Pet. 17-18 (citing cases); Pet. Reply 9-10 (responding to same point).

Second, the government (at 19 n.5) says that both *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), held that a finding of liability under state law would not impose a "requirement" and that this "premise" was rejected in *Bates*. *See* 544 U.S. at 443. To begin with, the point that state tort law can impose "requirements" did not originate with *Bates*, but more than 20 years earlier, *see Cipollone*, 505 U.S. at 521-22, and was recognized in *Lohr* itself. *See* 518 U.S. at 488 (plurality); *id.* at 500 (majority). More importantly, neither *Oja* nor *Niehoff* held that state-law liability *cannot* impose a requirement. Rather, those cases held that each state-law claim at issue did not "constitute a state requirement developed *'with respect to' a medical device*," as required by section 360k(a) and *Lohr*. *Oja*, 111 F.3d at 789 (quoting *Lohr*) (emphasis added); *see Niehoff*, 950 S.W.2d at 822 (state laws of general applicability not preempted under 21 C.F.R. § 808.1(d) and *Lohr*).

2. The Solicitor General's suggestion (at 19) that the government's about-face on the merits—first espousing a narrow reading of the MDA's express preemption provision and later a very broad one—will lead courts that have held that premarket approval is not preemptive to reconsider their holdings is unsupported by a single example and belied by the history of litigation in this area. Thus, although the government's own reversal is now more than three years old, no court

has reversed its prior position. Moreover, judges have dissented from the decisions of each of the two federal circuit courts to have addressed the issue since the government's new-found views were announced. *See* Pet. App. 43a (Pooler, J., dissenting); *Horn v. Thoratec*, 376 F.3d 163, 180 (3d Cir. 2004) (Fuentes, J., dissenting).

In addition, from 1996 (when the government filed its brief in *Lohr*), to 1997 (when it filed its brief in *Kernats*), through 2003, the government's view was that section 360k(a) does not generally preempt damages claims associated with PMA devices. Many courts nonetheless held the opposite. There is no reason to think that the government's decision to reverse itself will lead courts also to reverse themselves.

For two reasons, speculation that courts will alter their views in reaction to the government's about-face is particularly improbable here. First, in two recent cases, this Court refused to defer to the government's construction of an express preemption provision when the government's view had been inconsistent. *See Bates*, 544 U.S. at 449; *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000). Those cases make clear that statutory language, not the government's position *du jour*, is the primary basis for construing an express preemption provision. Second, the most relevant government viewpoint for purposes of construing the MDA's preemption provision, 21 U.S.C. § 360k(a), is not the one adopted in the government's most recent amicus brief, but the one adopted by the Food and Drug Administration ("FDA") in a regulation promulgated through notice-and-comment rulemaking. Accordingly, in *Lohr*, the Court did not give weight to the Solicitor General's amicus brief, but to 21 C.F.R. § 808.1, a regulation issued by the FDA in connection with its authority to exempt state requirements from preemption. *See Lohr*, 518 U.S. at 495-97. That regulation remains in effect and does not support the position taken by the government on the merits. *See id.*; Pet. 8,

20. Remarkably, the government's brief does not even cite section 808.1.

3. The great majority of the government's brief is devoted to arguing the *merits* of the question whether premarket approval of a medical device preempts state-law damages claims for personal injury caused by that device. In doing so, the government skims past the statutory language and makes no effort to reconcile its position with congressional intent, the "ultimate touchstone" of express preemption analysis. *Lohr*, 518 U.S. at 485; *Cipollone*, 505 U.S. at 516.

The Riegels strongly disagree with the government's argument. As construed in *Lohr*, section 360k(a) requires a comparison of a device-specific federal requirement with a state counterpart requirement "with respect to" medical devices. 518 U.S. at 500-01 (majority opinion). The government's argument, however, does not even attempt to operate within this rubric. And it ignores the distinction, described in its *Kernats* brief, between the general requirements of PMA and performance standards that impose specific requirements on particular devices. *See* 21 C.F.R. § 861.1(b); U.S. Br. in *Kernats* at 15 (making this distinction); *see also* Pet. 8 (examples of device-specific federal requirements); *Lohr*, 518 U.S. at 504 (Breyer, J., concurring) (example of device-specific state requirement).

Although this supplemental cert.-stage brief is not the place for a full discussion of the merits, two additional points are worth mentioning. First, the government (at 11) states that, after Medtronic's device was approved, the company "could not lawfully implement any changes that would affect safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior approval)." Here, there is no evidence that Medtronic ever sought FDA approval to make changes to address the defects alleged by the Riegels. Thus, any regulatory requirement that

the FDA approve such changes is beside the point. More fundamentally, the deficiency in the label of Medtronic's device could have been corrected without prior FDA approval, pursuant to 21 C.F.R. § 814.39(d)(2) (company may make labeling changes, prior to FDA approval, to "add or strengthen a contraindication, warning, [or] precaution," or to "add or strengthen an instruction that is intended to enhance the safe use of the device"). Medtronic never attempted to do so.

Although generally trying to distance this case from *Lohr*, the government (at 10) tries to use *Lohr* in support of a call for deference to the government's view. In *Lohr*, however, as noted above, the Court did not defer to the government's brief, but to an FDA regulation, 21 C.F.R. § 808.1, issued in 1979. Read in the context of the paragraph of the *Lohr* majority opinion from which they were pulled, the sentences quoted in the government's brief unambiguously address the weight to be accorded to that regulation. *See Lohr*, 518 U.S. at 496-97. Post-*Lohr* opinions explaining that the degree of weight accorded to an agency's views depends on, among other things, the consistency and formality of those views, further counsel against according substantial weight to the view of the merits stated in the government's brief, as opposed to the agency's longstanding regulation. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000); *cf. Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

4. The government (at 16-17) implies that its argument against preemption in *Smith Medical Systems Industries v. Kernats* was based on a proposed FDA interpretive rule that was about to be issued. The *Kernats* brief belies that implica-

tion. There, the government argued for four pages that PMA and IDE ("investigational device exemption") "do not displace state law standards of care or common law duties respecting the medical device" because they are not "device specific" requirements within the meaning of section 360k(a). U.S. Br. in *Kernats* at 15; *see id.* at 14-18. Those pages do not mention the proposed rule. Then, the government turned to the proposed interpretive rule and argued that the rule provided an independent reason for the Court to "defer review," not because the proposed rule affected the Solicitor General's view on the merits, but because the rule might affect the lower courts' views. *Id.* at 18.

In *Kernats*, aside from its view that the Court's review was not warranted because the holding that PMA does not preempt damages claims was correct, the government argued that because the decision below was not a final judgment under 28 U.S.C. § 1257, and because a new interpretive rule might influence the lower courts' views on the question presented, the Court should not grant that petition. Here, the Court has jurisdiction under 28 U.S.C. § 1254, and no relevant proposed rule is pending. Accordingly, the reasons argued by the Solicitor General for denying the petition in *Kernats* are not present. Here—almost ten years after the Solicitor General first noted the "division among the lower courts" that "would normally provide a strong justification for this Court to grant review and definitively resolve the conflict"—there is no jurisdictional hurdle, no pending rule, and no impediment to this Court's resolution of the longstanding conflict.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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